

Remarks

35 U.S.C. §112 Rejections

Rejection based on “plurality of substantially parallel layers”

The Examiner has rejected Claims 26 and 46-52 under 35 U.S.C. 112. The Examiner objects to the language “plurality of substantially parallel layers”, indicating that the Applicant has not pointed to portions of the Specification that supports this limitation and finding it to be “new matter” lacking adequate support and written description in the specification.

Applicant agrees with the Examiner that “plurality” can mean a multitude, but it is also conventionally used in patent claims to describe two or more elements. See Section 20, Plural Elements, Landis on Mechanics of Patent Claim Drafting (3rd. Edition), “...The recitation of “plurality” suggests the use of “at least two...” *ResQNet.com Inc. v. Lansa Inc.*, 346 F3d 1374 (CAFC 2003).

The Examiner has noted that the drawings and the specification of the present application disclose two layers: polymer and ceramic, as well as an interface region. The presence of two or more layers in the specification is sufficient antecedent basis for the term “plurality”, which in this instance is used in a conventional way to refer to “two or more.” (Some embodiments of the present invention described and illustrated in the specification feature more than two layers, e.g., FIG. 5 shows three layers 52, 54 and 60 and two interphase regions 62, 64.)

For the foregoing reasons, Applicant has left the terminology “plurality” in the claims. If the Examiner requires substitute language, such as “at least two” or “two or more”, those would be acceptable substitutes. Further, the Applicant would be willing

to amend the specification to insert the specific terminology "plurality" in the specification if the Examiner thinks it is necessary to do so.

Rejection of Claim 46 based on "plurality of porous polymer projections"

The Examiner has also inquired as to the basis for the terminology "plurality of porous polymer projections." Claim 46 has been amended and the term "projections" has been replaced with the term "extensions", a term which the Examiner has not objected to. The terminology "plurality" has been considered above. With regard to these polymer extensions, the present application is directed to a scaffold which has both physical/mechanical properties as well as chemical/compositional properties. This is a consequence of the problem that the scaffold is intended to address, viz., as a repair for a defect in force-bearing (e.g., weight-bearing joint) tissue of a living being. The scaffold therefore addresses the mechanical/structural demands of a force-bearing structure that must be compositionally and structurally compatible with physiologic processes, such a cell ingrowth, and with living tissue generally to compensate for and promote the healing of a tissue defect. As a result, the present invention is claimed both in terms of mechanical structure as well as composition. Both aspects are important to the present invention.

The "polymer extensions" are a mechanical feature of the present invention, which is shown in Figures 1 and 2 and described in the specification. For example, in paragraph 0023 of the application as published, the specification describes the interphase zone as exhibiting a microporous polymer foam located within the

macropores of a porous ceramic. Figure. 1 illustrates the extensions of the polymer 12 into the macropores of the ceramic 14. The extensions of the polymer are also depicted in cross-section in Figure 2, i.e., polymer 12 within macropores 15. In this particular instance, the macropores of the ceramic define the shape of the extensions of the polymer, in that the polymer infuses into the macropores and is solidified and foamed within the macropores via lyophilization. As a result, the polymer extensions of the interphase region fit in close, complementary, interlocking fashion within the macropores of the ceramic. This mechanical relationship provides a strong mechanical bond between the two layers, as well as a permeable interface.

Given the above-described amendment and comments, this basis for objection should be resolved.

Rejection of Claim 46 based on "Plurality of said plurality of extensions"

Claim 46 was rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner objects to the language "plurality of said plurality of extensions" in the second to last line of Claim 46 and has inquired as to the meaning of this phrase. Consistent with the foregoing consideration of the terminology "plurality," this phrase means "at least two" or "two or more" of said plurality of extensions. This allows Claim 46 to cover an embodiment where less than all of the plurality of extensions have microporosity. No amendment has been made in order to allow the Examiner to reconsider this point in light of the foregoing consideration of the term "plurality." If the Examiner believes the alternative language

“at least two” or “two or more” is preferable to the admittedly redundant-sounding “plurality of said plurality,” that substitution would be acceptable to Applicant.

In light of the foregoing, Applicant respectfully suggests that all rejections based on 35 U.S.C. 112 have been resolved.

Prior Art Rejections and Response Thereto

Claim 46

The Examiner has rejected Claim 46 under 35 U.S.C. 103(a) as unpatentable over U.S. Patent 6,376,573 to White et al. hereinafter “White,” in view of Ries et al. U.S. Patent 4,623,553, hereinafter “Ries.”

Claim 46 has limitations that distinguish from the proposed combination of White and Ries, in that the claim specifies forming an interlocking interface between a ceramic body and a polymer layer, wherein the interface has a plurality of polymer extensions extending into a corresponding plurality of macropores on the surface of the ceramic layer. In contrast, White, teaches away from retaining polymer in ceramic **macropores**, which is considered a problem (Col. 2, l 46-49). Instead, White specifies that the macropores are preferably drained of collagen, leaving only the **micropores** of the ceramic containing collagen (see e.g., Col. 4., l 49-52).

White also teaches away from Claim 46 in that White teaches that the micropores of the hydroxyapatite are too small to support the ingrowth of bone cells and therefore they may be **filled with** collagen (which inhibits bone cell ingrowth). This is a teaching away from the benefit of the collagen itself having micropores through some process, since, according to White, the collagen present in the micropores is

inaccessible to bone ingrowth. Given the foregoing teaching away there is no credible motivation for combining White and Ries.

Even if there were a motivation to combine White with Ries, the combination does not provide the features of the present invention as claimed in Claim 46. Neither reference discloses forming a scaffold with a layer of polymer on a ceramic body with an interlocking interface of polymer extensions extending into the macropores of the ceramic body. For each of the foregoing reasons, Applicant respectfully submits that Claim 46 patentably distinguishes over the proposed combination of White and Ries.

Claims 26 and 47

The Examiner has rejected Claim 26 under 35 U.S.C. 103(a) as unpatentable over an article appearing in the publication "Biomaterials" by Niederauer et al. The Examiner has rejected Claim 47 under 35 U.S.C. 102 or in the alternative under 35 U.S.C. 103(a) as obvious over Niederauer.

Claim 26 is a method claim and 47 is an apparatus claim. Both have been rejected based upon Nedierauer, reciting common reasons. Claims 26 and 47, while different types of claims, have a similar scope, have been amended in this amendment in a similar way and lend themselves well to simultaneous consideration herein for the purposes of efficiency and to avoid redundancy. Claims 26 and 47 were previously expressed in a manner which, inter alia, attempted to call out the macroscopic mechanical/structural features of the ceramic and polymer layers and how they were conjoined to distinguish over the substantially different construct described in Niederauer. Claims 26 and 47 have been further amended to achieve this end by

specifying that: (1) the ceramic layer consists essentially of ceramic and (2), that the first and fourth surfaces each have a surface area of approximately the same scale as the cross-sectional area of the scaffold taken generally perpendicular to the direction of layer stacking (first dimension).

The description of the embodiments of the present invention in the specification and the examples given therein all provide antecedent basis for the composition of the ceramic layer as consisting essentially of ceramic. The ceramic layer has pores therein which may receive non-ceramic material (such as the polymer, which extends into the macropores) but that this is not incompatible with the ceramic layer consisting essentially of ceramic. By way of analogy, a box may consist essentially of cardboard, which accommodates in a space therein a pair of leather shoes. The composition of the box is cardboard regardless whether leather shoes are present or not within the box.

Antecedent basis exists for the claimed surface area of the first and fourth surfaces (shown, e.g., in Figures 1-5), in that all surfaces have a surface area. Similarly, the scaffold, by definition, has a cross-sectional area and that cross-sectional area can be measured at any orientation, including in an orientation that is generally perpendicular to the direction that the layers are stacked. Figures 1-5 show layers, e.g., 12 and 14 that are stacked along a first dimension and further showing that the layers have surfaces that have an area approximating that of the cross-section of the scaffold taken perpendicular to the first dimension. This dimensional language is offered as an indicator that the claimed surfaces are macroscopic and of a scale approximating that of the whole scaffold. The foregoing amendments make explicit that which is implied in

common parlance by reference to "a layer" and are in response to the Examiner's broad interpretation of the term "layer."

In contrast, Niederauer describes a laminated scaffold having a "cartilage phase" and a "bone phase." The cartilage phase of Niederauer is composed of a mixture of polymers, potentially including polyglycolic acid fibers. The bone phase can be either a mixture of polymers with or without polyglycolic acid fibers or a polymer matrix with non-polymeric inclusions, viz., bioglass particles (53-90 um) or medical grade calcium sulfate particles. An additional polymer film may be included in the laminate. The cartilage phase, the bone phase and the polymer film are glued together using a solvent. In rejecting Claim 26, it appears that the Examiner is interpreting the "bone phase" described above as equivalent to the ceramic layer of Claim 26. Claim 26 was amended both in the previous amendment and in the present amendment to avoid this interpretation and to make the difference between Niederauer and the claimed invention clear.

Stepping back from the intricacies of claim language, one can see that the invention disclosed in the present application is significantly different in form and function from that disclosed in Niederauer. As pointed out in Törmälä (Col. 2, l 8-27) ceramic powder-polymer composites (like Niederauer) have a disadvantage in that the presence of binding polymeric material prevents direct contact between the bio-ceramic and bone tissue. Bone tissue does not have an affinity to grow on the surface of polymers and as a consequence the growth of new bone and the healing of tissue is slowed. The "bone phase" of the Niederauer scaffold is exactly what Törmälä describes as the disadvantaged material - a ceramic powder-polymer composite, such that when

the "bone phase" is placed near a bone, the living bone tissue would be slowed from contacting the ceramic inclusions by the polymer matrix. In contrast, the present invention has a layer of ceramic that contacts the bone and therefore encourages more rapid bone in-growth. Given this substantial difference between the two technologies, the goal is to present claims which clearly distinguish the present invention from Niederauer.

The amendments made herein specifying that the ceramic layer consists essentially of ceramic and has first and second surfaces, each having an area approximating the cross-sectional area of the whole scaffold should clearly and patentably differentiate from the bone phase or other teachings of Niederauer. More particularly, the bone phase of Niederauer is a composite which contains substantial portions of polymer - between 50% to 80%, so therefore it does not "consist essentially of ceramic". If one wishes to interpret the ceramic particle inclusions (bone glass particles) of the bone phase as the "ceramic layer" of claims 26, not only does this violate any reasonable interpretation of "layer" in this context, but such particles do not have surfaces of the proper dimensional scale as now called for in Claim 26. This amendment points out that the ceramic layer has a scale like that of the scaffold. The purpose of this dimensional specification is to distinguish from the ceramic particles of Niederauer, which are clearly not of the same scale as the scaffold.

In the Office Action the Examiner suggests that the interface between the ceramic and polymer layers of the present invention, as claimed in Claims 26 and 47 is the same as the interface between the "bone phase" and the "cartilage phase" of Niederauer. Given the amendments to Claim 26 and 47 describing the dimensions and

composition of the ceramic layer and the polymer layer, as well as the specified structural interconnections, (polymer extensions extending from the polymer layer into macropores in a surface of the ceramic layer of the dimensional scale as the scaffold), one can readily appreciate that these layers are quite different from the "cartilage phase" and the "bone phase" of Niederauer and that the interface between them can not be the same as between the "cartilage phase" and the "bone phase" of Niederauer.

More particularly, the "bone phase" of Niederauer does not consist essentially of ceramic, there is no mention of there being any macropores on the ceramic particles (bioglass) included in the "bone phase" of Niederauer and therefore they can not be simply surmised to exist. Since there are no known macropores on the ceramic particles, there is no accommodation for any extensions from a polymer layer, e.g., the "cartilage phase" proposed by the Examiner, that will insert therein. Even if there were macropores in the ceramic particles of Niederauer, one would expect that the polymer of the polymer matrix of the "bone phase" would fill them, rather than the polymer of the "cartilage phase", which is separately prepared and subsequently glued to the "bone phase". There is no indication that the solvent gluing process of the "bone phase" to the "cartilage phase" results in emptying any polymer of the "bone phase" from the ceramic particles of the "bone phase" in order to in-fill with polymer from the "cartilage phase." For each of the foregoing reasons, Applicant respectfully submits that amended Claims 26 and 47 patentable distinguish over Niederauer.

In light of the foregoing, Applicant has declined at this time to provide Declaration or Affidavit evidence pertaining to the non-porosity of the solvent glued interface between the bone phase and the cartilage phase of the Niederauer scaffold

(since it does not appear necessary).

Rejection of Claims 47-51 under Niederauer in view of Törmälä

The Examiner has rejected Claim 47-52 under 35 U.S.C. 103(a) as unpatentable over Niederauer in view of Törmälä et al. U.S. 5,084,051.

The Examiner does not express in the Office Action how the combination of Törmälä and Niederauer applies to Claim 47, so Applicant relies upon the prior arguments described above in this Amendment to distinguish Claim 47 from Niederauer. If the Examiner wishes to apply the combination to Claim 47 in a subsequent Office Action, Applicant will respond. As to the claims which depend from Claim 47, Applicant respectfully submits that those claims are patentable based upon their dependency from a patentable claim, Claim 47. In addition, the dependent claims 48-51 recite additional novel features. For example, Claim 52 reinforces and amplifies the compositional transition from the ceramic layer (now defined to be consisting essentially of ceramic and having a scale like that of the whole scaffold) to the polymer layer, each with their explicitly recited surfaces, extensions of polymer into the macropores of the ceramic layer, etc.

New Claim Added

Applicant thanks the Examiner for her suggestion as to the possibility of claiming the present invention in product-by-process form. New Claim 53 is presented herein pursuant to that suggestion and expresses the combination of patentable features as are present in Claim 26, but in product-by-process form.

Applicant's attorney thanks the Examiner for conducting a rigorous examination and for performing her duty as a public advocate. If such advocacy had been more prevalent in the patent system, there would be less talk today of trolls and junk patents. Notwithstanding the benefits of rigorous examination, the Examiner is earnestly requested to consider this amendment and to aid in bringing this case to a fruitful conclusion, keeping in mind the potentially beneficial function of the patent system, viz., to provide an incentive for the development of beneficial technology, such as apparatus and methods for treating painful and disabling defects in joint tissues that would otherwise not be developed, but for a mechanism that feasibly encourages investment to promote such development.

Applicant's attorney has sought to present allowable claims in light of the Examiner's observations and in light of the prior art. Applicant's attorney respectfully requests the Examiner to allow the claims presented herein. In the event that some detail as to the expression of the invention in the claims is somehow unacceptable, Applicant's attorney respectfully requests the Examiner's assistance to formulate language which in her opinion is satisfactory. Applicant's attorney will likely endorse any reasonable formulation.

Application No. 09/892,993
Reply to Office Action mailed August 25, 2009

A fee in the amount of \$220 for an additional independent claim is believed to be due. The Examiner is authorized to charge this \$220 fee to Deposit Account No. 503571. If any additional fees are due, the Examiner is hereby authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

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Dated: August 25, 2009